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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 11/00 — A1

(11) International Publication Number: WO 00/37133

(43) International Publication Date: 29 June 2000 (29.06.00)

(21) International Application Number: PCT/US99/30657

(22) International Filing Date: 21 December 1999 (21.12.99)

(30) Priority Data:
09/217,501 21 December 1998 (21.12.98) US

(71) Applicant: WE PHARMACEUTICALS, INC. [US/US]; P.O. Box 1142, Ramona, CA 92065 (US).

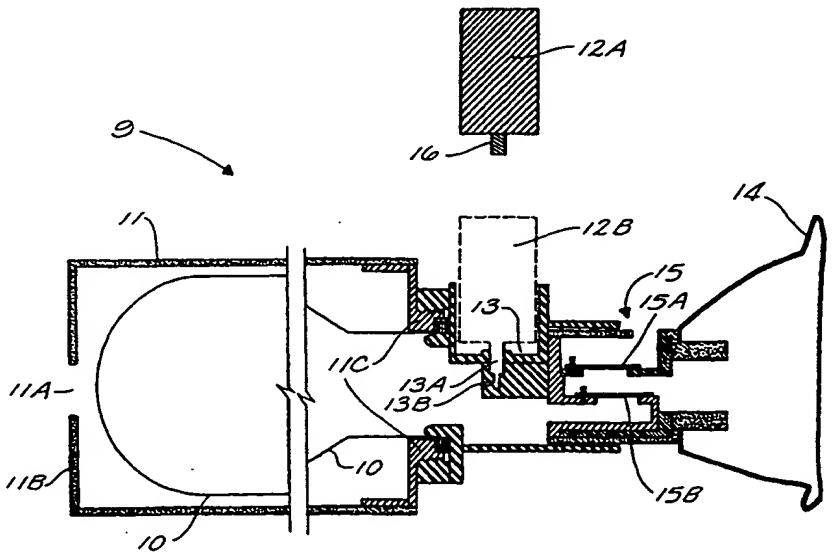
(72) Inventor: MECIKALSKI, Mark; 7580 North Calle Sin Desengano, Tucson, AZ 85718 (US).

(74) Agent: OGRAM, Mark, E.; 8040 South Kolb Road, Tucson, AZ 85706 (US).

(81) Designated States: AU, CA, JP, NZ, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: INFANT INHALER



(57) Abstract

An infant inhaler in which the aerosol medication (12A) is communicated into a flexible bag (10). Using a mask (14), during inhalation, the medicated air within the flexible bag (10) is drawn into the infant's lungs; exhalation from the infant is exhausted into the atmosphere. By watching the deflation of the flexible bag, the care–giver is appraised of the progress of the medication's inhalation. The entire assembly is held with one hand allowing the infant to be cradled in the other arm. Refilling of the flexible bag with ambient air is accomplished by inverting the apparatus which causes the valves (15A, 15B) therein to open and allow ambient air into the flexible bag (10). Refilling the flexible bag (10) with medication (12A) is done using a single hand by pressing the aerosol bottle (12A) against the apparatus.

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INFANT INHALER

Background of the Invention:

This invention relates generally to medical inhalers and more particularly to inhalers adapted for use on an infant.

Medicating the lungs of a patient having respiratory problems is an ancient art. Indigenous natives have long had sweat lodges which used special herbs for the treatment of a variety of ailments.

In more modern times, the same technique is still being used, the introduction of a medication into the lungs of the patient to either treat the lungs themselves or to be absorbed into the blood stream through the lungs. What has changed dramatically is the effectiveness of the medications themselves and the range of ailments that these medications are capable of reaching.

The key to all of these medications remains, how to effectively deliver the proper dosage into the patient's lungs?

To address this problem, a variety of "inhalers" have been developed. These inhalers range in application from the asthma spray applied by the patient herself to inhalers which are used on patients who are unable to administer the inhaler themselves. It is this latter group which is of particular interest as often the physician, nurse, or other care-giver must determine if the proper dosage has been administered and not left within the inhaler.

This problem is accentuated for infants who have extremely low respiratory pressures and very small tidal displacements. Since the tidal displacement is so very small, it often requires many respirations for the full dosage to be administered.

To address this problem, a variety of instruments have been developed. One such instrument is described in United States Patent number 5,427,089, entitled "Valved Auxiliary Device for Use With Aerosol Container" issued to Kraemer on June 27, 1995. This instrument is designed to be placed over the mouth and nose of an

infant while the proper dosage is administered into a rigid mixing reservoir. The infant's normal respiration draws in from the mixing reservoir and exhales into the environment.

Unfortunately, this apparatus is particularly difficult to use. Using the instrument of Kraemer requires the use of two hands by the care-giver while the medication is being administered into the mixing reservoir. This means that the infant must either be held by a third party or be in a lying position on a bed or examining table. Either of these methods is difficult to administer.

With rigid mixing reservoirs, each breath entrains ambient air, so that the medication concentration declines with each subsequent breath.

It is clear that there is a need for an improved infant inhaler.

Summary of the Invention:

Within the present invention, an infant inhaler, the aerosol medication is communicated into a flexible bag. The flexible bag is protected by a rigid body so that the care-giver does not inadvertently press upon the flexible bag.

The aerosol medication is applied to the bag using a traditional aerosol applicator which delivers a burst of medication into the air contained within the flexible bag.

Using a mask, during inhalation, the medicated air within the flexible bag is drawn into the infant's lungs; exhalation from the infant is exhausted into the atmosphere. A valve system, located between the flexible bag and the mask, assures that the infant must breathe from the flexible bag and that the exhalation is prevented from entering the flexible bag.

In this manner, each breath from the infant contains the same dosage and is delivered under ambient air pressure. The infant is not required to "suck"; normal breathing is all that is required.

By watching the deflation of the flexible bag, the care-giver is appraised of the progress of the medication's inhalation. When the flexible bag is fully deflated, the care-giver knows that the full dosage has been given, even if it takes only a few breaths or many breaths from the infant.

Administering the medication is also facilitated as the entire assembly is held with one hand of the care-giver, allowing the infant to be cradled in the other arm. Using only a single hand, the care-giver is able to: place and hold the mask over the infant's nose and mouth; administer the proper dosage from the aerosol applicator into the flexible bag; and, monitor the application of the medication as the aerosol bag deflates.

Refilling of the flexible bag with ambient air is accomplished by inverting the apparatus which causes the valves to open and communicate ambient air to the flexible bag. While the "upright" position is the preferred position for refilling the flexible bag, other positions are available so long as the position is not too similar as that taken when using the instrument with an infant.

Refilling the flexible bag with medication is done with one hand by pressing the aerosol bottle against the apparatus using fingers from the supporting hand. The care-giver uses only one hand for the instrument, the other arm and hand is free to cradle the infant during the procedure.

The instrument of this invention provides the care-giver feedback as to whether the infant was inhaling the medication or not. If the flexible bag does not begin collapsing upon placement of the mask on the infant's face (indicating a poor seal between the mask and infant), the mask position is easily adjusted to assure that the infant is breathing from the instrument and is not drawing air from the environment. The flexible bag also allows continuous monitoring of the seal, so adjustments can be made during the entire inhalation period.

In the instrument of this invention, the hand actuating the aerosol canister is close to the mask so that a good seal is more easily obtained. The instrument is ideally designed so that it requires only one hand, leaving the other hand free to support the infant.

Ideally the instrument of this invention is used in a position similar to that used in bottle feeding an infant, which is a very natural and comfortable position.

Further, the design of the instrument allows it to be comfortably shaken with only one hand, without the danger of the aerosol canister falling out, so that multiple doses may be given with only one hand operation. In the preferred embodiment, the securing of the aerosol canister to the inhaler is accomplished through frictional contact, and by the ability of the care-giver's hand to hold the canister in place.

To provide the maximum efficiency of aerosol delivery it is important to have a flexible bag which empties as completely as possible with the force generated by infant breathing. In order to do this, and still have a flexible bag durable enough to be cleaned, the ideal flexible bag is made from a thin elastomer film. The preferred embodiment uses a silicone rubber due to its adequate flexibility with a wall thickness providing good durability.

The shape of the flexible bag ideally resembles a child's balloon, that is, it has a narrow neck. This shape has been found to keep the deflation pressure low, even when

the bag was almost totally collapsed. Re-inflation of the flexible bag is assisted if silicone rubber is used. By choosing the proper thickness of the flexible bag, an infant is able to completely deflate the flexible bag, yet, when the bag is exposed to ambient air pressure from within, it will self inflate. The re-inflation of the bag is ideally accomplished when the bag is hanging freely.

As noted earlier, to protect the flexible bag, it is enclosed within a chamber or sleeve. The ideal chamber is a circumferential clear plastic tube. One end of the tube has an opening in it which allows air to enter and allows the flexible bag to collapse. The other end of the tube is attached to a section which holds the aerosol canister and the valves.

An alternative embodiment uses a chamber/sleeve which is provided with slotted windows to permit the flexible bag to be visible therethrough. In this manner, the care-giver is able to monitor the status of the flexible bag.

The valves in this invention are relatively thick and are ideally attached at only one side, so that the entire dimension of the valve is allowed to flex and respond to pressure changes. This produces a more durable valve, which is still very responsive.

The invention, together with various embodiments thereof, will be more fully explained by the accompanying drawings and the following descriptions.

Drawings in Brief:

Figure 1 is a side perspective view of the preferred embodiment of the invention illustrating the entire infant inhaler.

Figures 2A and 2B illustrate the use of the inhaler of figure 1 in application on an infant patient and during "re-charge" of the flexible bag.

Figure 3 is a frontal view of the preferred embodiment illustrating the one-hand refilling of the flexible bag with aerosol medication.

Figures 4A, 4B, 4C, and 4D are cutaway views of the preferred valve system illustrating the valves during rest, inhalation, exhalation, and "re-charge" of the flexible bag respectively.

Drawings in Detail:

Figure 1 is a side perspective view of the preferred embodiment of the invention illustrating the entire infant inhaler.

Inhaler 9 is adapted to receive aerosol medication canister 12A into seat 13 where it is held using frictional contact. Once positioned, release 16 of canister 12B fits into receptacle 13A. When pressed downward, release 16 discharges a medicated mist which is communicated via channel 13B into flexible bag 10.

Flexible bag 10 is contained within protective sleeve 11. Opening 11A assures that the exterior of flexible bag 10 is subjected to ambient air pressure; hence, as flexible bag 10 is deflated due to the inhalation of the infant (not shown), the patient's breathing is not stressed but continues under normal conditions.

Monitoring the deflation of flexible bag 10 is facilitated due to the transparent nature of sleeve 11. In some embodiments, sleeve 11 has slot windows to assist in the viewing of flexible bag 10.

In some embodiments, to increase the visibility of flexible bag 10, the material of flexible bag 10 is tinted during manufacture so that the bag has a readily seen color. In other embodiments, the bag is transparent to facilitate viewing the aerosol plume.

Flexible bag 10 is easily changed by un-screwing sleeve 11 via screw-attachment 11C to reveal flexible bag 10.

Base 11B of protective sleeve 11, is flat to allow inhaler 9 to be easily placed upon a table top. Once resting on base 11B, inhaler 9 is vertical which permits flexible bag 10 to re-inflate naturally.

Once the interior of flexible bag 10 has been charged with medication, as outlined above, the medicated air is communicated via valve system 15 to the infant patient. During inhalation, the medicated air from flexible bag 10 is communicated through valve system 15; in this state, valve 15B is opened and valve 15A is closed. During exhalation, the exhale is exhausted when valve 15A opens and valve 15B closes.

In this manner, only medicated air is inhaled, and all of the patient's exhalation is exhausted into the environment and not into flexible bag 10. The medicine/air content of each breath taken by the infant is identical.

Mask 14 is secured to inhaler 9 and is used to provide a tight fit over the infant's nose and mouth. In use, the care-giver is able to monitor the deflation of flexible bag 10 to assure that mask 14 is properly sealed to the face of the patient. If flexible bag 10 is deflating during the breathing of the patient, then a proper seal of mask 14 is obtained; if flexible bag 10 is not deflating, then the care-giver must adjust inhaler 9 (and by extension mask 14) so that a proper seal is obtained. Mask 14 is optionally rotated 180° to permit operation with either hand.

Figures 2A and 2B illustrate the use of the inhaler of figure 1 in application on an infant patient and during "re-charge" of the flexible bag.

Once the flexible bag has been charged with medication, inhaler 9A is placed over the nose and mouth of infant 22. Due to the arrangement of inhaler 9A, a single hand 20A is used to support and position inhaler 9A while the other hand 21 is freed to support infant 22.

In order to "re-charge" or inflate the flexible bag (not shown), as shown in figure 2B, using a single hand 20B, inhaler 9B is placed into a position whereby the valves are opened allowing ambient air to enter the flexible bag.

Canister 12B is positioned on inhaler 9A allowing the user's hand 20A to compresses canister 12B to charge the flexible bag with medication. Further, the entire assembly (including canister 12B) is easily shaken by a single hand 20B to provide a more efficient release of the medication from canister 12B.

Ideally, canister 12B is secured to inhaler 9A through a frictional grip to prevent canister 12B from being dislodged during shaking or use of inhaler 9A. The operator's hand is also holding the canister in place.

Figure 3 is a frontal view of the preferred embodiment illustrating the one-hand refilling of the flexible bag with aerosol medication.

Using a single hand 20C, the care-giver grasps inhaler 9C and squeezes, as indicated by arrow 30. This pressure causes canister 12B to release its medication into the flexible bag. In application, inhaler 9C, in this illustration, is held in the right hand 20C, with the mask 14 away from the operator.

Note that canister 12B is vertical, as it must be to properly discharge the

medication. Inhaler 9C is held in this position while the whole unit is shaken, and then canister 12B is actuated to spray into the flexible bag.

Once the flexible bag is charged, the inhaler is placed on the infant's face. In this embodiment, the nasal portion 14A of mask 14 is positioned at about a right angle to canister 12B. This relationship of canister 12B to mask 14 provides a more comfortable position of the care-giver's wrist during treatment.

Since the inhaler is placed onto the infant's face, without requiring the re-positioning of the hand position , inhaler 9C naturally rotates with the arm so that mask 14 is in proper vertical position, and canister 12B is now horizontal.

Figures 4A, 4B, 4C, and 4D are cutaway views of the preferred valve system illustrating the valves during rest, inhalation, exhalation, and "re-charge" of the flexible bag respectively.

Referring to figure 4A, the "relaxed state", in this state valve 40A and 41A are both closed. This is the state where the mask has not been placed over the nose and mouth of the infant or the state between inhalation and exhalation.

During inhalation, figure 4B, valve 40B is closed, while valve 41B opens allowing a flow of medicated air 43 to be communicated from the flexible bag to the lungs of the patient.

During exhalation, figure 4C, valve 41C is closed and valve 40C is opened allowing exhaled air 44 to be exhausted.

Referring to figure 4D, to re-inflate the flexible bag, inhaler 9 is placed in a vertical, or almost vertical position, as indicated by arrow 42. In this position, valve 40D and valve 41D fall open to allow ambient air 45 to pass through to the flexible bag.

It is clear that the present invention creates a highly versatile and effective infant inhaler.

What is claimed is:

1. An infant inhaler comprising:

a) a mask configured to be placed over an infant's nose and mouth;

b) a flexible bag;

c) a rigid body member totally containing said flexible bag, said rigid body secured to said mask;

d) a valve system contained with said rigid body, said valve system configured to communicate air to said mask from said flexible bag during patient inhalation, and to exhaust air from said mask during patient exhalation; and,

e) an aerosol medication bottle connectable to said rigid body such that exhaust from said aerosol medication bottle is communicated to said flexible bag.

2. The infant inhaler according to claim 1, wherein said rigid body includes a reservoir containing said flexible bag such that said flexible bag is viewable within said reservoir.

3. The infant inhaler according to claim 2, wherein said flexible bag is colored.

4. The infant inhaler according to claim 2, wherein said flexible bag is substantially transparent.

5. The infant inhaler according to claim 2, wherein said reservoir, said valve system, and said mask are substantially in a linear relationship.

6. The infant inhaler according to claim 5, wherein said aerosol medication bottle is substantially at right angles to said reservoir.

7. The infant inhaler according to claim 5, wherein said aerosol medication

bottle is activatable by pressing said aerosol medication bottle against said rigid body member.

8. The infant inhaler according to claim 7, wherein said rigid body member and said aerosol medication bottle are configured to be grasped with a single hand.

9. The infant inhaler according to claim 1, wherein said valve system allows ambient air to enter said flexible bag when said rigid body is in a pre-determined position.

10. The infant inhaler according to claim 1,

a) wherein said reservoir includes a base surface configured to support said infant inhaler when said infant inhaler is placed on a surface; and,

b) wherein said valve system is in an open condition allowing ambient air to enter said flexible bag when said infant inhaler is supported by said base surface.

11. The infant inhaler according to claim 10, wherein said flexible bag is removable from said rigid body member.

12. An inhalation kit comprising:

a) an applicator configured to be held with a single hand, said applicator having,

1) a mask configured to be placed over an infant's nose and mouth,

2) a flexible bag contained within said applicator, and,

3) a valve system configured to communicate air to said mask from said flexible bag during patient inhalation, and to exhaust air from said mask during patient exhalation; and,

b) an aerosol medication bottle connectable to said rigid body such that exhaust from said aerosol medication bottle is communicated into said flexible bag.

13. The inhalation kit according to claim 12, wherein said flexible bag is viewable within said applicator.

14. The inhalation kit according to claim 13, wherein said flexible bag, said valve system, and said mask are substantially in a linear relationship.

15. The inhalation kit according to claim 14, wherein, once connected to said applicator, said aerosol medication bottle is activatable by pressing said aerosol medication bottle against said applicator.

16. The inhalation kit according to claim 15, wherein, once assembled, said applicator and said aerosol medication bottle are configured to be grasped with a single hand.

17. The inhalation kit according to claim 12, wherein said valve system allows ambient air to enter said flexible bag when said applicator is in a pre-determined position.

18. A medicated aerosol applicator assembly comprising:

a) a mask configured to be placed over an infant's nose and mouth;

b) a rigid body member containing a flexible bag;

c) a valve system connected to said rigid body member and said mask, said valve system configured to communicate air to said mask from said flexible bag during patient inhalation, and to exhaust air from said mask during patient exhalation; and,

d) an aerosol medication bottle connectable to said rigid body such that

exhaust from said aerosol medication bottle is communicated into said flexible bag.

19. The medicated aerosol applicator assembly according to claim 18, wherein said rigid body, said valve system, and said mask are substantially in a linear relationship.

20. The medicated aerosol applicator assembly according to claim 19, wherein said aerosol medication bottle is substantially at right angles to said rigid body member.

21. The medicated aerosol applicator assembly according to claim 20, wherein said aerosol medication bottle is activatable by pressing said aerosol medication bottle against said rigid body member.

22. The medicated aerosol applicator assembly according to claim 21, wherein said rigid body member and said aerosol medication bottle are configured to be grasped with a single hand.

23. The medicated aerosol applicator assembly according to claim 18, wherein said valve system allows ambient air to enter said flexible bag when said rigid body is in an up-right position.

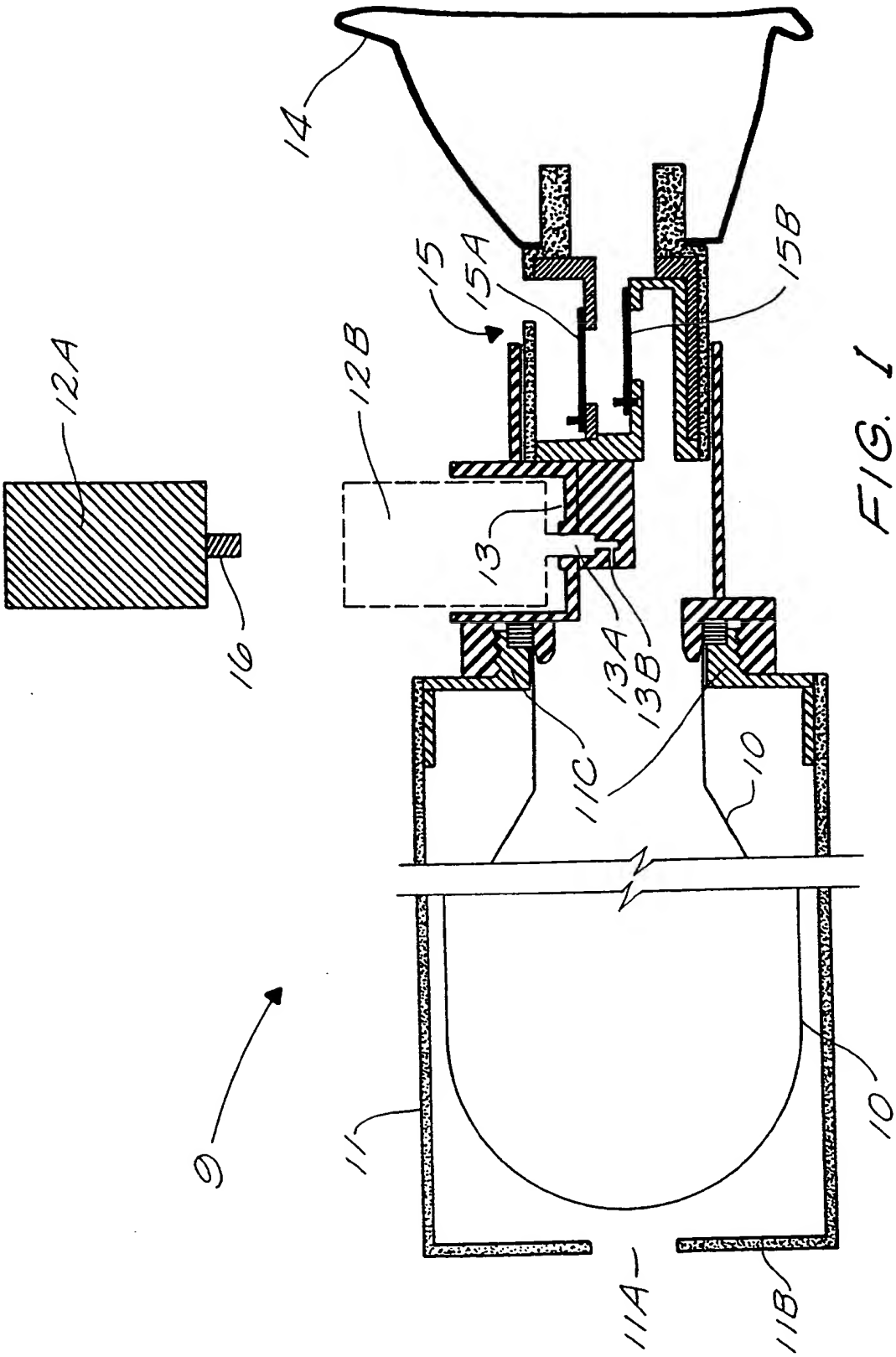

FIG. 1

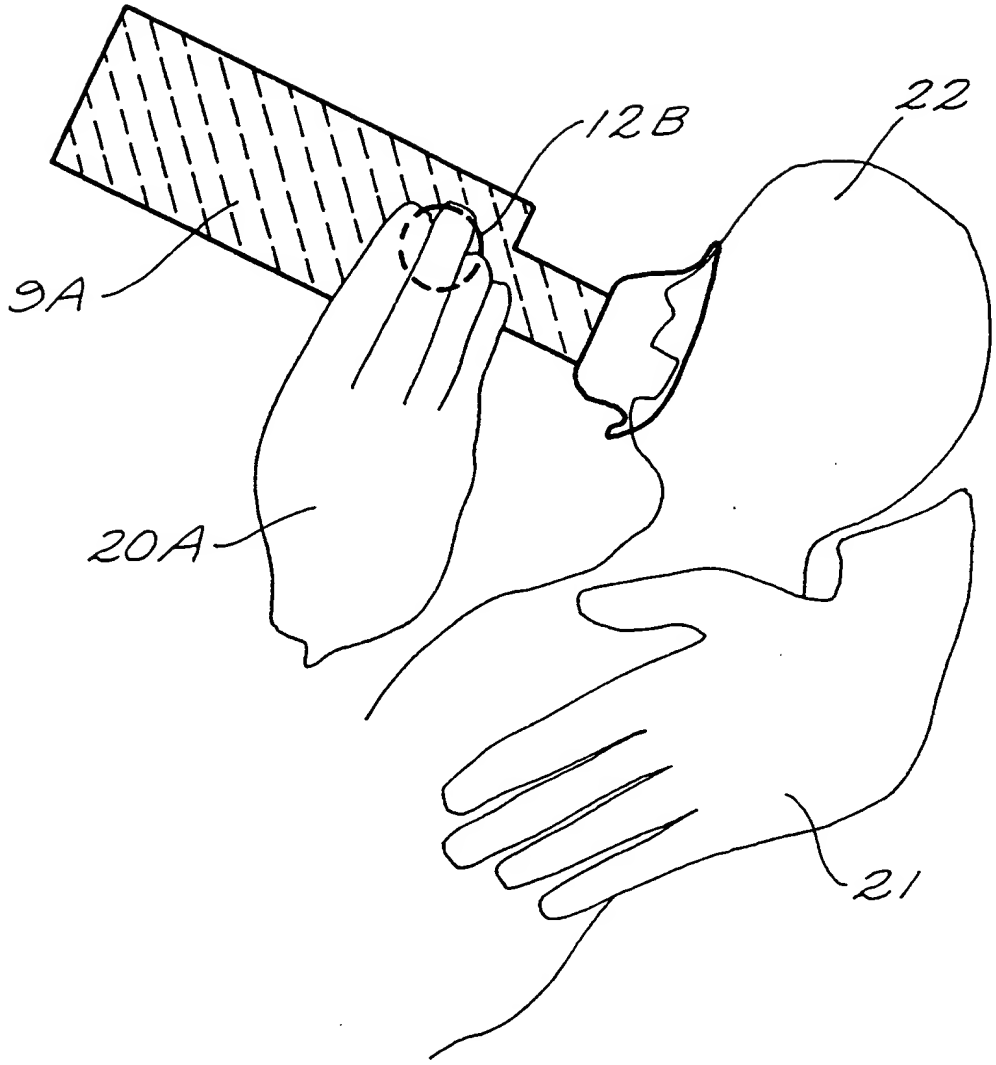

FIG. 2A

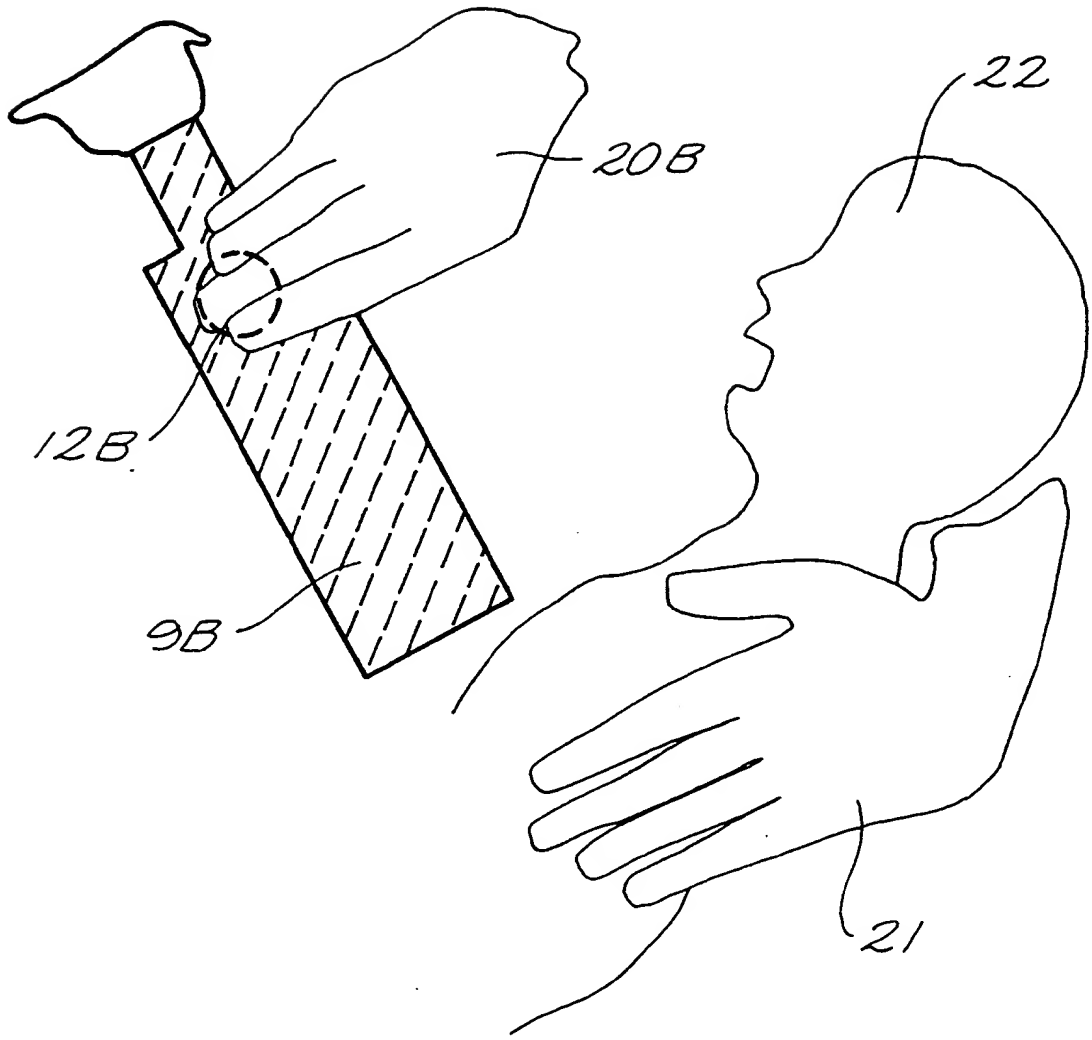

FIG. 2B

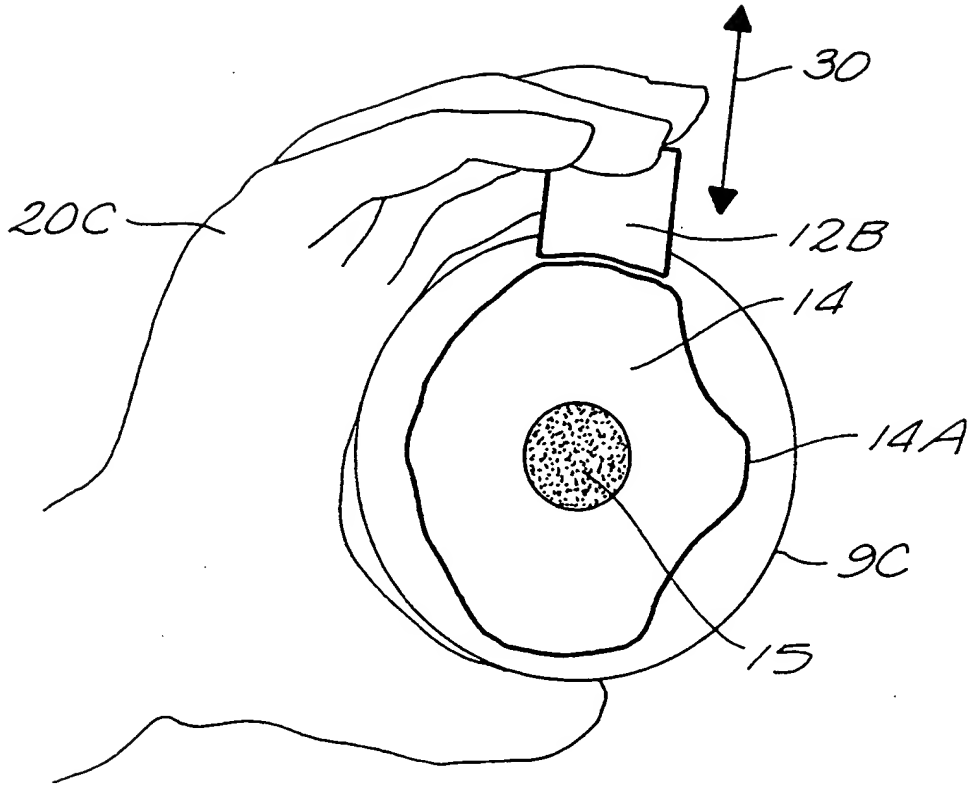

FIG. 3

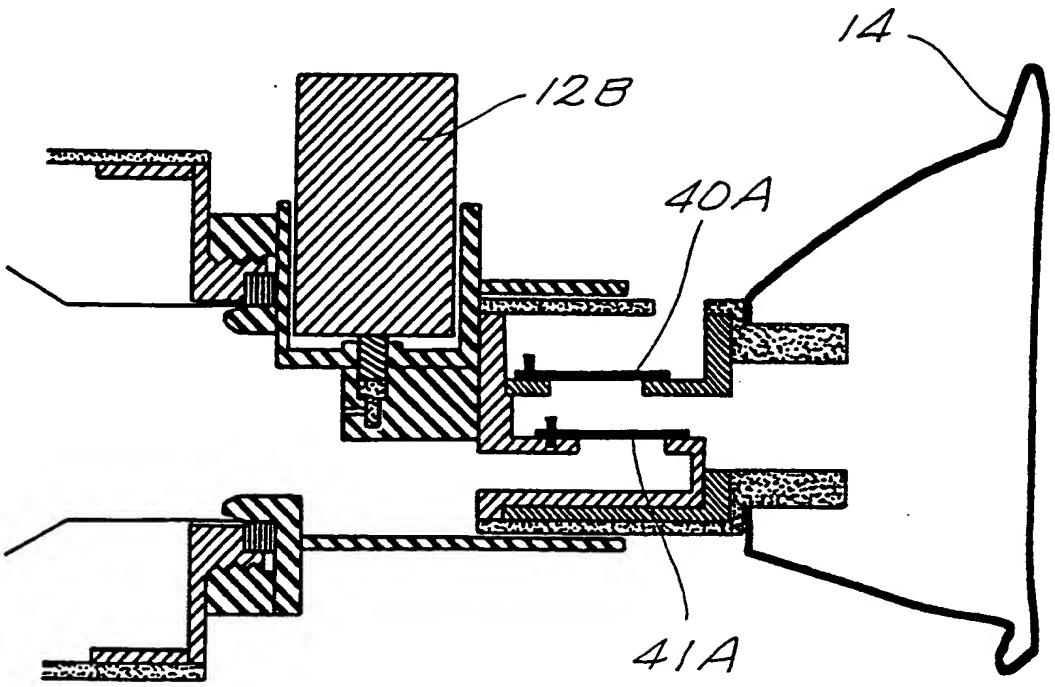

FIG. 4A

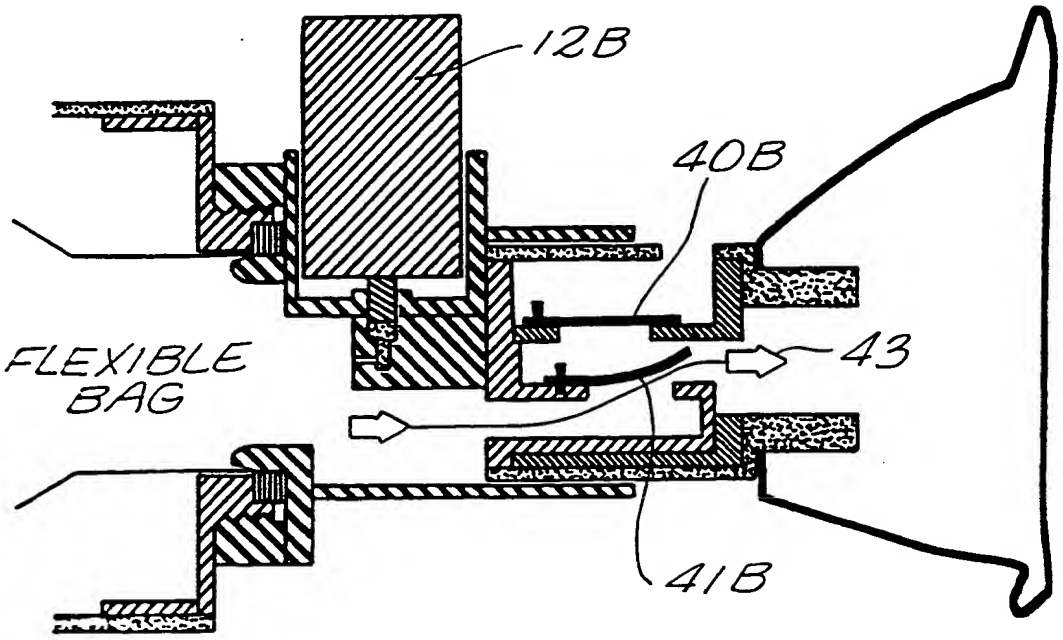

FIG. 4B

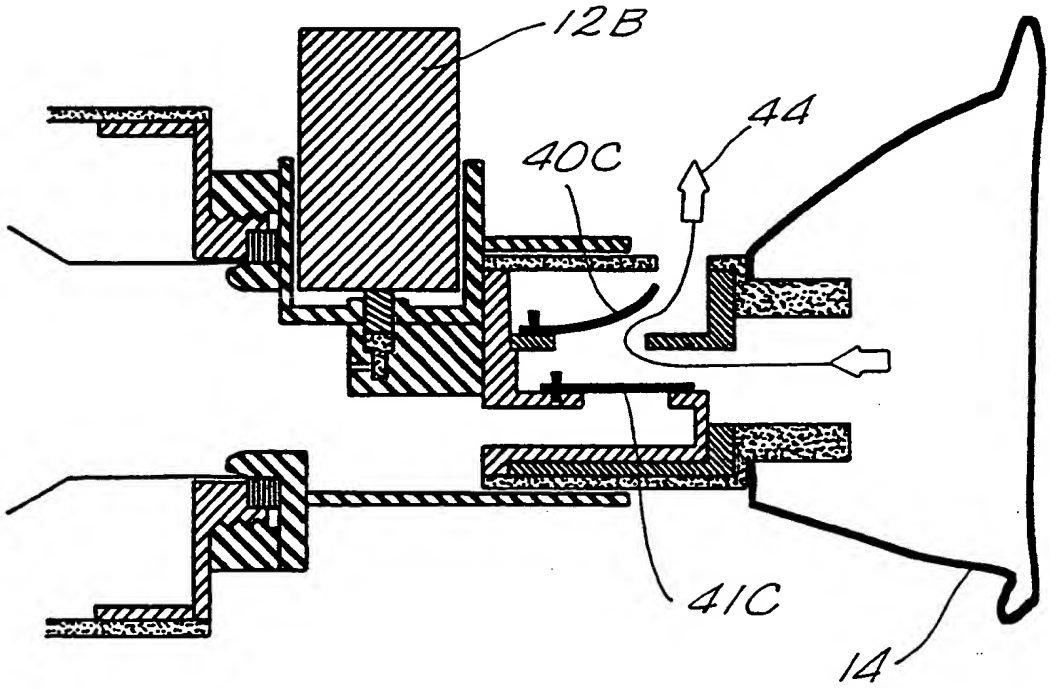

FIG. 4C

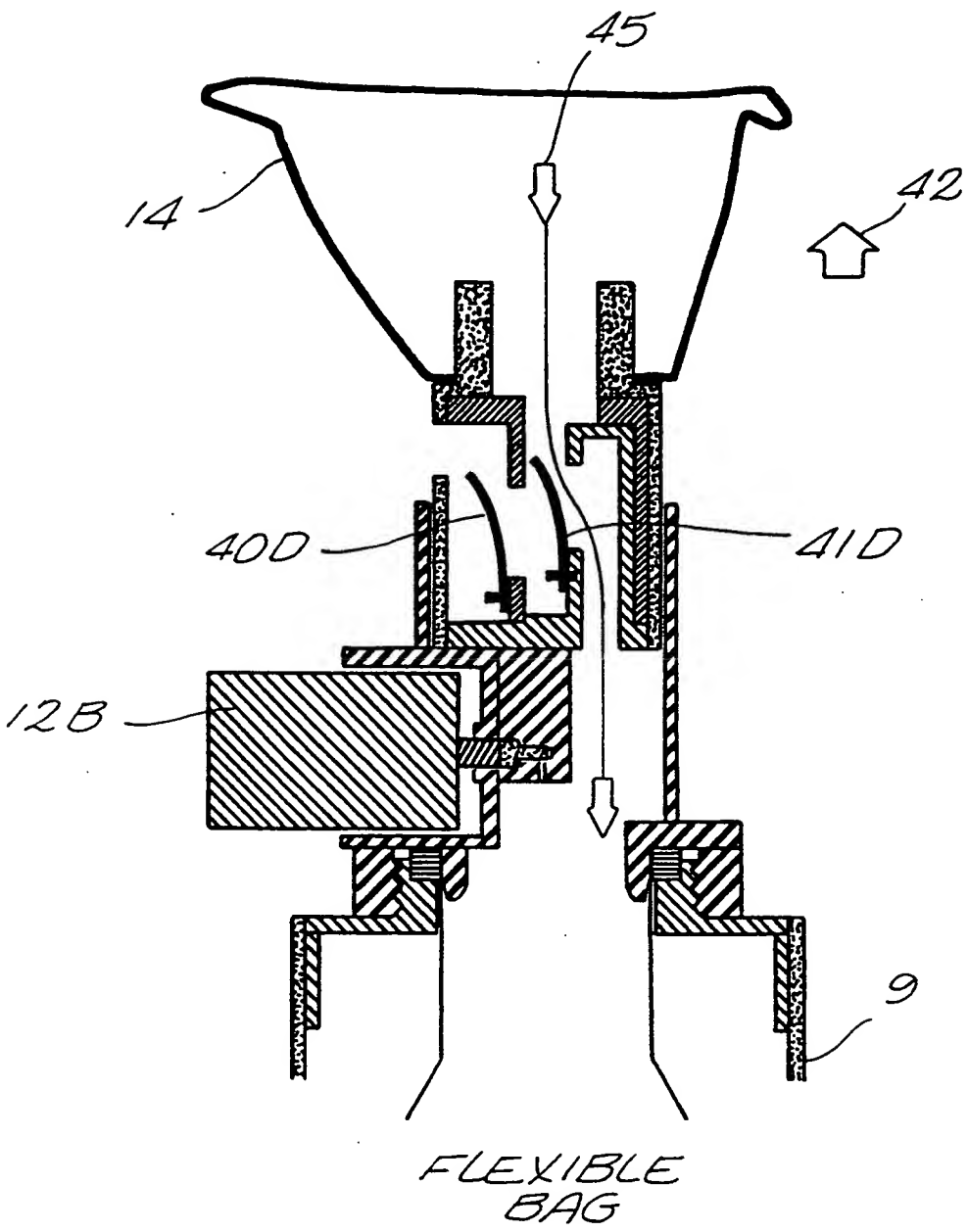

FIG. 4D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/30657

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61M 11/00
US CL :128/200.23, 203.12, 203.28, 203.29
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/200.14, 200.21-200.23, 203.12, 203.23-203.25, 203.28, 203.29, 204.28, 205.13, 205.14, 205.17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST
Search Terms mask, bag, bellow, bulb, aerosol, valve medicine, medicament, pharmaceutical, breathing

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 773,018 A (Magne) 10 November 1934, Fig., 2 and supporting text.	1-23
Y	US 5,701 886 A (RYATT) 30 December 1997, Fig. 3 and supporting text.	1, 12, 18
Y	UK 2 104 394 A (ROMANAT) 09 March 1983, figures and supporting text.	1-23
Y	US 5,762,063 A (COATES et al.) 09 June 1998, port 12, and supporting text.	1, 12, 18
Y	US 5,842,467 A (GRECO) 01 December 1998, bottle (20), bag (10), and supporting text.	1-23
Y	US 5,628,305 A (MELKER) 13 May 1997, mask (6), bag (2), housing (1), and supporting text.	1-23

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
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Date of the actual completion of the international search 17 FEBRUARY 2000	Date of mailing of the international search report 06 APR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOSEPH F. WEISS, JR. Telephone No. (703) 305-0323

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/30657

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document. with indication. where appropriate. of the relevant passages	Relevant to claim No.
Y	US 5,318,016 A (MECIKALSKI) 07 June 1994, bottle (16), bag (14), housing (10)(12), mask (60), and supporting text.	1-23

Form PCT/ISA/210 (continuation of second sheet)(July 1992)*